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09/880,253	06/13/2001	Joseph Attila Rothnagel	1371	7843

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EXAMINER

MCKILVEY, HERRY ALAN

ART UNIT

PAPER NUMBER

1636

DATE MAILED 12/31/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/880,253

Applicant(s)

ROTHNAGEL ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4-5, 7-9, 11-13, 15-16, 22-23, 25-28, 42-43, 45-51, 75-76, 78-79, 81-88, 90-91, and 93-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising removing one or more ATG triplets, classified in class 435, subclass 91.42.
- II. Claims 1, 3-5, 7-9, 11-12, 14-16, 32-33, 35-38, 42-43, 45-51, 75, 77-79, 81-87, 89-91, and 93-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising introducing one or more ATG triplets, classified in class 435, subclass 91.42.
- III. Claims 1-2, 4, 6-8, 10-11, 17-18, 20-22, 24-25, 29-31, 42, 44-51, 75-76, 78, 80-88, 90, and 92-95, only as

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drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising removing one or more AUG triplets, classified in class 435, subclass 91.42.

IV. Claims 1, 3-4, 6-8, 10-11, 17, 19-21, 32, 34-35, 39-42, 44-51, 75, 77-78, 80-87, 89-90, and 92-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising introducing one or more AUG triplets, classified in class 435, subclass 91.42.

V. Claims 1-2, 7, 9, 11-13, 16, 22, 26, 28, 42-43, 45-51, 75-76, 81-88, and 93-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising removing one or more GTG triplets, classified in class 435, subclass 91.42.

VI. Claims 1, 3, 7, 9, 11-12, 14, 16, 32, 35-36, 38, 42-43, 45-51, 75, 77, 81-87, 89, and 93-95, only as drawn

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to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising introducing one or more GTG triplets, classified in class 435, subclass 91.42.

VII. Claims 1-2, 7, 10-11, 17-18, 21-22, 29, 31, 42, 44-51, 75-76, 81-88, and 93-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising removing one or more GUG triplets, classified in class 435, subclass 91.42.

VIII. Claims 1, 3, 7, 10-11, 17, 19, 21, 32, 35, 39, 41-42, 44-51, 75, 77, 81-87, 89, and 93-95, only as drawn to a method of modulating the expression of a genetic sequence, wherein said sequence comprises an ORF having an ATG corresponding to an authentic translation site, said method comprising introducing one or more GUG triplets, classified in class 435, subclass 91.42.

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- IX. Claims 52-53 and 55-60, drawn to isolated nucleic acid comprising ATG, classified in class 536, subclass 23.1.
- X. Claims 52 and 54-60, drawn to isolated nucleic acid comprising AUG, classified in class 536, subclass 23.1.
- XI. Claims 61-68, drawn to genetic construct, classified in class 435, subclass 320.1.
- XII. Claims 69-70 and 74, drawn to method for modulating expression of a genetic sequence comprising creating or removing one or more ATG pseudo-translation initiation triplets, classified in class 435, subclass 91.4.
- XIII. Claims 69, 71, and 74, drawn to method for modulating expression of a genetic sequence comprising creating or removing one or more GTG pseudo-translation initiation triplets, classified in class 435, subclass 91.4.
- XIV. Claims 69, 72, and 74, drawn to method for modulating expression of a genetic sequence comprising creating or removing one or more AUG pseudo-translation initiation triplets, classified in class 435, subclass 91.4.

XV. Claims 69 and 73-74, drawn to method for modulating expression of a genetic sequence comprising creating or removing one or more GUG pseudo-translation initiation triplets, classified in class 435, subclass 91.4.

Groups I-XV are comprised of multiple inventions which are the products or methods drawn to different and distinct sequences which are chemically, biologically, and structurally different and distinct from each other, which do not render obvious each other, and thus are patentably distinct.

Applicants must elect a single invention which is the product or method drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

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The inventions are independent and/or distinct, each from the other because of the following reasons:

Inventions of Groups I-VIII and XII-XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-VIII and XII-XV comprise steps which are not required for or present in the methods of the other groups. The end result of the methods are different because of the different steps in the methods. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The products of Groups IX-XI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of one group is not required to product the products of the other groups (which can be produced synthetically or self-replicated). Therefore, the inventions of these groups are capable of supporting separate patents.

Inventions of Groups IX-XI and Groups I-VIII and XII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different



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effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups IX-XI are not used in or produced by the methods of Groups I-VIII and XII-XV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the non-patent literature search required for each group is not co-extensive with the other groups because the search of each group requires a search for materially different elements not in common with the other groups, thus causing a burden to search together, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Conclusion**

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

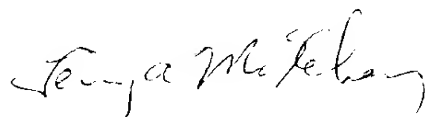
NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
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December 29, 2002